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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,532	02/09/2001	Clive Wood	GNN-012CP	8383

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EXAMINER	
QIAN, CELINE X	
ART UNIT	PAPER NUMBER
1636	13

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/780,532	Applicant(s) WOOD ET AL.	
	Examiner Celine X Qian	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1,9-12,15,21-24,26 and 29-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8,13,14,16-20,25,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence compliance letter* .

DETAILED ACTION

Claims 1-38 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group V in Paper No. 12 is acknowledged. Applicant further elected TRADEα and NFkβ signal pathway. The election is made with traverse. The traversal is on the ground(s) that 1) there is no search burden to rejoin the invention of Group V and VIII because Group VIII is directed to modulating cell proliferation using an anti-TRADE antibody which encompasses the invention of Group V. 2) TRADEα and TRADEβ share high degree of homology and are likely to interact with similar sequences. 3) Modulation of TRADE molecule activity frequently results in changes in one or more signaling pathway, thus do not impose an undue burden to search all of them in a single application.

This is not found persuasive for following reasons. Group V is drawn to a method of modulating cell proliferation comprising contacting cell with a polypeptide that modulates the activity of a TRADE molecule, classified in class 530, subclass 350. The modulator may be agonist, antagonist or mutant TRADE molecule which is not encompassed by the invention of Group VIII (drawn to modulating cell proliferation using TRADE antibody, classified in class 530, subclass 387.1). Because the different classification and divergent subject matter, a search of both groups in a single application is not co-extensive. Although modulation of TRADE molecule activity would result in changes in one or more signaling pathway, a search of all signaling pathway is not co-extensive, and would have been burdensome. However, considering the close related nature of TRADEα and TRADEβ, both molecules will be examined.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1, 9-12, 15, 21-24, 26 and 29-38 are withdrawn from consideration for being directed to non-elected subject matter. Claims 2-8, 13, 14, 16-20, 25, 27 and 28 are currently under examination with respect to NFkβ signaling pathway.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

The sequences in Figure 1-3 do not have sequence identifier.

Claim Objections

Claims 3-5, 13, 17-20 and 25 are objected to for containing non-elected subject matter. For example, claim 3 depends on either claim 1 or 2. However, claim 1 does not belong to the elected subject matter. Amending the claims such that they are only directed to elected inventions.

Claim 27 is objected to for containing grammatical error and improper Markush group format. The grammatical error is on line 3: "consisting of: of:" The proper Markush format

should be in the format of "...an intestinal cell, and a lung cell." Appropriate correction is required.

Specification

The disclosure is objected to because it contains embedded hyperlinks on pages 10, 46, 47 and 50. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-8, 13, 14, 16-20, 25, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of

the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether the whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The terms "a TRADEα or a TRADEβ polypeptide," "a TRAIN polypeptide, a αOAF065 polypeptide," or "a TRADE family member" recited in above claims are not clearly described in the specification. The specification discloses the cloning of two novel receptors of TNF receptor superfamily, TRADEα and TRADEβ. The specification defines the term "TRADE" as TNF Receptor family member Associated with Death protein. The specification further discloses that "TRADE family polypeptide" is intended to include proteins having a TRADE structural domain or motif and having sufficient amino acid or nucleotide sequence identity with a TRADEα or β molecule. Examples of such family member include TRADEα, TRADEβ, Apo4, TRAIN, αOAF065 and βOAF065 (see page 9-10). However, a search of prior art reveals that the only known members of the TRADE molecules are TRADEα and TRADEβ. Although Apo4, TRAIN, αOAF065 and βOAF065 all belong to the TNF receptor superfamily, they do not belong to TRADE family. The specification fails to describe what is the structural domain or motif of the TRADE polypeptide and what constitutes "sufficient sequence identity" to TRADEα or β. As such, what "TRADE family member" encompasses is unclear. In addition, TRAIN polypeptide appears to

refer to a single receptor (same for αOAF065 polypeptide) in the art. It is also unclear what other family members the TRAIN polypeptide encompasses. Therefore, the specification fails to describe a representative number of species of the genus "TRADE family member" etc. by their complete structure or other identifying characteristics.

The claims are directed to a method of modulating cell proliferation comprising contacting a cell with an agent that modulates the activity of a TRADE molecule. The specification only discloses that the agent can be TRADE homologs, agonists, antagonists antibodies or antisenses. However, the specification fails to describe what specific characteristics and common structures these agents must share. As such, the specification fails to describe the complete structure and a representative number of species of the broadly claimed genus of "agents." Therefore, the specification fails to describe the invention in such a way to convey one skilled in the art that the inventors had possession of claimed invention at the time the application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8, 13, 14, 16-20, 25, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2-8, 13, 14, 16-20, 25, 27 and 28, the terms "a TRADEα polypeptide," "a TRADEβ polypeptide," "a TRADE polypeptide," "a TRAIN polypeptide," "a αOAF065 polypeptide" and "a TRADE family member" render the claims indefinite because it is unclear

what polypeptide Applicants are referring to. The specification only discloses one TRADEα and one TRADEβ, and there is only one TRAIN receptor and αOAF065 documented in the art. As such, the metes and bounds of the claims cannot be established.

Regarding claim 4, the recitation of "the cell is a carcinoma or an adenocarcinoma" renders the claim indefinite because it is unclear how a single cell can be a carcinoma or an adenocarcinoma. It appears that Applicants are referring to a carcinoma cell. Appropriate clarification is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
November 18, 2002

Gerald A. Schaffer
PATENT EXAMINER

Application No.: 09/780532

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: _The sequences listed in Figures 1-3 do not have sequence identier.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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